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American National Standard

Advancing Safety in Hea<mark>lthcare Technology</mark>

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> Medical electrical equipment — Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems



American National Standard

ANSI/AAMI/IEC 60601-2-47:2012/(R)2016 (Revision of ANSI/AAMI EC38:2007)

Medical electrical equipment — Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory Advancing Safelectrocardiographic systems

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Approved 20 July 2012 by plete copy of this AAMI document, contact AAMI at +1-977-249-8226 or visit www.aami.org.

Approved 1 August 2012 and reaffirmed 6 January 2017 by **American National Standards Institute, Inc.**

Abstract: Specifies the basic safety and essential performance of ambulatory electrocardiographic (ECG) systems. Within the scope of this standard are systems of the following types: a) systems that provide continuous recording and continuous analysis of the ECG allowing full re-analysis giving essentially similar results. The systems may first record and store the ECG and analyze it later on a separate unit or record and analyze the ECG simultaneously. The type of storage media used is irrelevant with regard to this standard; and b) systems that provide continuous analysis and only partial or limited recording not allowing a full re-analysis of the ECG.

Keywords: ECG, electrocardiograph, electromedical equipment, holter monitors

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Printed in the United States of America

ISBN 978-1-57020-449-4

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Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

IEC 60601-1:2005 ANSI/AAMI ES60601-1:2005/(R)2012 and ANSI/AAMI ES60601-1:2005/A:2210/(R)2012 ANSI/AAMI ES60601-1:2005/A:2210/(R)2012 ANSI/AAMI ES60601-1:2005/A:2210/(R)2012 C1 Identical to Corrigendum 1 8 2 IEC 60601-1:2:2007 ANSI/AAMI ES60601-1:2:005/(R)2012 Identical variations IEC 60601-2:2:007 ANSI/AAMI IFA60601-1:1:2:007/(R)2012 Identical IEC 60601-2:2:007 ANSI/AAMI/IEC 60601-2:2:007 Identical IEC 60601-2:2:003 ANSI/AAMI/IEC 60601-2:2:009 Identical IEC 60601-2:2:003 ANSI/AAMI/IEC 60601-2:0:008 Identical IEC 60601-2:2:2:009 ANSI/AAMI/IEC 60601-2:0:209 Identical IEC 60601-2:2:2:0:01 ANSI/AAMI/IEC 60601-2:2:2:009 Identical IEC 60601-2:2:2:0:01 ANSI/AAMI/IEC 60601-2:2:2:0:01 Identical IEC 60601-2:2:2:0:01 ANSI/AAMI/IEC 60601-2:2:2:0:01 Identical IEC 60601-2:2:0:009 ANSI/AAMI/IEC 60601-2:0:0:009 Identical IEC 60601-2:2:0:0:00 ANSI/AAMI/IEC 60601-2:0:0:009 Identical IEC 60601-2:0:0:0:0:0:0:0:0:0:0:0:0:0:0:0:0:0:0:0	International designation	U.S. designation	Equivalency
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Committee representation

Association for the Advancement of Medical Instrumentation

Electrocardiograph (ECG) Committee

The adoption of IEC 60601-2-47 as a revision of ANSI/AAMI EC38:2007 was initiated by the AAMI ECG Committee, which serves as a U.S. sub-TAG (technical advisory sub-group) for IEC/SC 62D. U.S. representatives played an active role in developing the IEC standard.

At the time this document was published, the AAMI ECG Committee had the following members:

Cochairs:	Richard A. Sunderland Ahmet Turkmen, BS MS PhD Brian J. Young
Members:	Robert William Bain, CBET, Baltimore Medical Engineers & Technician Society Robert E. Bruce Scott Coggins, Covidien Prakash C. Deedwania, MD, The VA Medical Center Laura Dhatt, Physio-Control Sreeram Dhurjaty, Dhurjaty Electronics Consulting LLC Richard Diefes, ECRI Institute Greg Downs, Spacelabs Medical Inc. Arthur R. Eddy, Jr. Advancing Safety in Healthcare Technology James J. Greco, Medapprove Inc. Richard Gregg, Philips Electronics North America Janice M. Jenkins, PhD, University of Michigan College of Engineering Carolyn Lall, Draeger Medical Systems Inc. Dongping Lin, PhD Walter G. Lloyd, Childrens Hospital Boston Th Peter W/Macfatlane; Royabinfirmary, AAMII guidance document and is int Luis A. Melendez, Partners Healthcare George Moody, Massachusetts Institute of Technology Cadathur Rajagopalan, PhD SMIELEF, Mindray DS DSA theasing decision. Linda Ricci, FDA/CDRH Johann-Jakob Schmid, Schiller AG F Obnathan Steinberg, MD/St Lukes Roosevelt Hospital Center Contact AAMI at Richard A. Sundergand, Welchallof, or visit www.aami.org. Ahmet Turkmen, BS MS PhD, University of Wisconsin-Stout Jeffrey Wiser, 3M Healthcare Ted Yantsides, Conmed Corp Brian J. Young, GE Healthcare
Alternates:	Mark J. Callahan, Covidien Kejian Chen, 3M Healthcare Yu Chen, PhD, Draeger Medical Systems Inc. Steve Duke, Physio-Control Charles S. Ho, PhD, FDA/CDRH Richard Richardson, GE Healthcare Serkan Sezer, Schiller AG Donald Stewart, Spacelabs Medical Inc. Anna Varlese, Conmed Corp John J. Wang, Philips Electronics North America Yinqi Zhang, Spacelabs Medical Inc.

NOTE--Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.

Background of ANSI/AAMI adoption of IEC 60601-2-47:2012

As indicated in the foreword to the main body of this document (page ix), the International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising of all national electrotechnical committees. The United States is one of the IEC members that took an active role in the development of this standard, which was developed by the IEC Technical Subcommittee 62D, Electromedical equipment, maintenance team (MT) 22 on Electromedical diagnostic and patient monitoring equipment.

U.S. participation in IEC/SC 62D is organized through the U.S. Technical Advisory Group for IEC/SC 62D, administered by the Association for the Advancement of Medical Instrumentation (AAMI) on behalf of the U.S. National Committee of the American National Standards Institute. The U.S. made a considerable contribution to this International Standard.

AAMI encourages its committees to harmonize their work with International Standards to the extent possible. Upon review of the final draft International Standard of IEC 60601-2-47:2012, the AAMI ECG Committee, which serves as a U.S. Technical Advisory sub-Group to IEC/SC 62D, decided to adopt it verbatim as a revision of ANSI/AAMI EC38:2007.

The members of the AAMI ECG Committee and the US experts to the IEC/SC 62D MT22 would like to acknowledge that much of the language used for the requirements, testing and rationale in this document was taken directly from the ANSI/AAMI EC57:1998. It was agreed among those involved with the development of this particular standard that this would be the best approach to reach consensus in the harmonization efforts to adopt IEC 60601-2-47 as a replacement of ANSI/AAMI EC38:2007.

The creation of IEC 60601-2-47:2012 represents a deliberate effort to harmonize the standard with ANSI/AAMI EC38:2007 in order to achieve a single particular standard for ambulatory electrocardiographic systems. This standard incorporates the requirements and testing deviations that were previously adopted as deviations in ANSI/AAMI EC38:2007, which addressed the issues of algorithm database testing, frequency response, and pacemaker detection performance. This standard also introduces the definition of essential performance for ambulatory electrocardiographic systems.

AAMI and ANSI procedures require that standards be reviewed every five years and, if necessary, revised to reflect technological advances that may have occurred since publication. Intended to allow potential purchasers to evaluate the content AAMI (and ANSI) have adopted other IEC and ISO standards. See the Glossary of Equivalent Standards for a list of

AAMI (and ANSI) have adopted other IEC and ISO standards. See the Glossary of Equivalent Standards for a list of IEC and ISO standards adopted by AAMI, which gives the corresponding U.S. designation and the level of equivalency with the IEC and ISO standard.

For a complete copy of this AAMI document, contact AAMI at The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as advances are made in technology and as new data come to light.

This standard reflects the conscientious efforts of concerned health care professionals and medical device manufacturers to develop a standard for those performance levels that can be reasonably achieved at this time.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 4301 N. Fairfax Dr. Suite 301, Arlington, VA 22203-1633.

NOTE-This background does not contain provisions of the American National Standard, *Medical electrical equipment* – Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory *electrocardiographic systems* (ANSI/AAMI/IEC 60601-2-47:2012), but it does provide important information about the development and intended use of the document.

NOTE- Beginning with the foreword on page ix, this American National Standard is identical to IEC 60601-2-47:2012.

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT -

Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and his one areas, access to AEC marks of conformity UEO is not responsible for any services carried out by independent certification applies rchasers to evaluate the content
- 6) All users should ensure that they have the latest edition of this publication asing decision.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoevery whether direct of indirect, or for costs (including legal fees) and expenses arising out of the publication, use of or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International standard IEC 60601-2-47 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 2001. It constitutes a technical revision. This edition was revised to align structurally with the 2005 edition of IEC 60601-1.

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62D/963/FDIS	62D/980/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- Test specifications: italic type.
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type.
 Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Plant 2 is Forthe perpose stor this fstandard / the lauxiliary verburnent and is

- "shall" means that compliance with a trequise near or sate strist mandatory contoning liance with this standard; of the document before making a purchasing decision.
- "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard. MI document, contact AAMI at
- "may" is used to describe a7pendissible way it is achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

INTRODUCTION

This particular standard concerns the basic safety and essential performance of AMBULATORY ELECTROCARDIOGRAPHIC SYSTEMS. It amends and supplements IEC 60601-1 (third edition 2005): *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the general standard. The requirements of this particular standard take priority over those of the general standard.

A "General guidance and rationale" for the requirements of this particular standard is included in Annex AA.

It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, this annex does not form part of the requirements of this standard.



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American National Standard

ANSI/AAMI/IEC 60601-2-47:2012/(R)2016

MEDICAL ELECTRICAL EQUIPMENT -

Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems

201.1 Scope, object and related standards

Clause 1 of the general standard¹ applies, except as follows:

201.1.1 Scope

Replacement:



Advancing Safety in Healthcare Technology

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are aditiovered by specific requirements unthist standard except in 7.2.13 and 8.4.1.6.1.the general standard tial purchasers to evaluate the content

of the document before making a purchasing decision. NOTE See also 4.2 of the general standard.

Within the scope of this standard are systems of the toto wing types intact AAMI at

- a) systems that provide continuous recording and continuous analysis of the ECG allowing full re-analysis giving essentially similar results. The systems may first record and store the ECG and analyze it later on a separate unit, or record and analyze the ECG simultaneously. The type of storage media used is irrelevant with regard to this standard;
- b) systems that provide continuous analysis and only partial or limited recording not allowing a full re-analysis of the ECG.

The safety aspects of this standard apply to all types of systems falling in one of the abovementioned categories.

If the AMBULATORY ELECTROCARDIOGRAPHIC SYSTEM offers automatic ECG analysis, minimal performance requirements for measurement and analysis functions apply. MEDICAL ELECTRICAL EQUIPMENT covered by IEC 60601-2-25 and IEC 60601-2-27 are excluded from the scope of this standard.

¹ The general standard is IEC 60601-1:2005, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.